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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,278	02/22/2001	Michal Linial	P-1476-US	9776

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EXAMINER

ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/601,278

Applicant(s)

LINIAL ET AL.

Examiner

Marianne P. Allen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-23 and 27-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 2-23 and 27-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claims 1 and 24-26 have been cancelled. Claim 28 has been newly introduced.

Applicant's arguments filed 12/2/04 have been fully considered but they are not persuasive and/or are moot in view of the new ground(s) of rejection set forth below.

The rejection of claims 1, 17, 18, and 22 over Jones et al. is withdrawn in view of the amendments to the claims.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

The prior Office action denied priority to PCT/IL99/00057 citing a lack of a certified English translation. Review of the record reflects that the instant application was accepted as a national stage filing (35 USC 371) of PCT/IL99/00057 and that a copy of the application in English was submitted 7/31/00. As such, applicant is entitled to priority of the PCT/IL99/00057 filing date.

Abstract

Applicant is again requested to supply the abstract on its own sheet of paper to prevent processing difficulty with the printer should this application issue as a patent.

Election/Restrictions

Claims 14-16 and 19-20 were previously withdrawn as being directed to a non-elected species. The species election is hereby withdrawn and the full breadth of claims 2-23 and 27-28 have been fully examined on the merits.

Claim Objections

Claims 2, 16, 27, and 28 are objected to because of the following informalities: Claims 2, 27, and 28 contain typographical errors. It appears that –local—rather than “focal” consideration was intended in part a) iv, –clusters—rather than “dusters” was intended in part a) v and that –fourth—rather than “forth” was intended in part b) ii. In claim 16, it appears that –polynucleotide-- rather than “pofynucleotide” was intended. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claim 28 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described

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in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a new matter rejection.

Applicant has newly introduced claim 28 without pointing to basis in the specification for an article comprising a storage medium. No basis is apparent for this article.

Claims 2-13, 19-22, and 27-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for identifying nucleic acid and amino acid sequences that are similar, does not reasonably provide enablement for non-sequence molecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are broadly directed to comparing chemicals of all structures (claim 22), complex sugars (claim 21), glycoproteins (claim 19), and immunoglobulins (claim 21). While the specification provides guidance on performing the method for amino acid sequences that can be compared for similarity by algorithms such as BLAST, FASTA, and Smith-Waterman (and by analogy nucleic acid sequences), the specification does not provide guidance for how to perform the method for these other types of molecules. There is no guidance on what standard measures of similarity to use and how to form clusters to result in a hierarchical organization of molecules. Note that immunoglobulins are multi-chain proteins and glycoproteins have carbohydrate moieties attached to the backbone and as such, comparison of one amino acid sequence to another is insufficient.

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Claims 2-23 and 27-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is directed to an automatic method of classifying molecules having similar biologic function. Claim 27 is directed to system for automatically classifying molecules having similar biologic function. Claim 28 is directed to an article comprising a storage medium having instruction stored therein for an automatically classifying molecules having similar biologic function.

However, the claims are confusing in that the steps do not achieve the result of the preamble goal of the method. The steps may identify molecules that are highly structurally related but none of the steps of the method speak to biological function. While similar structures may have similar function, the claims possess no limitations making that connection.

In addition, part b) of the independent claims is directed to a submethod where the position of a selected molecule in the database is automatically determined. However, the claims are confusing in that the steps do not achieve the result of the preamble goal of this submethod. That is, none of the steps make any determination of position as required by this part of the claim. As amended, claim 2 recites "position of a selected molecule in said database." It is unclear if this is intended to mean that the molecule is present in and selected from within the database of part a) or whether a molecule is selected from elsewhere and its position within the database of part a) is determined. Based on the language of claim 27 for inputting a selected molecule, it appears that the latter is intended but the method steps do not make clear where the

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molecule of interest is selected from or how. If the molecule to be selected is input by a user then it appears that this is not an “automatic” process. Clarification is requested.

Part a) vi recites “analyzing said groups of the related clusters” without making clear what type of analysis is to be performed. That is, the particular, positive, active steps required to go from related clusters to a hierarchical organization of the molecules is not set forth in the claims. It is unclear what portion of the analysis in the specification applicant intends this step to represent. Applicant is reminded that limitations from the specification cannot be read into the claims. See also part a) ii, iv, and v which recite “identifying groups of clusters using local consideration,” “determining the relationship,” and “analyzing said first set of expectation values.” These are similarly unclear.

Claim 3 recites that a “connection is established.” The claim is unclear as to what the nature of this connection is. Is a piece of information stored in the database? Is it with respect to every molecule in the cluster or some other way?

Claim 4 is confusing in reciting “said cluster.” There are several clusters recited in claims 2 and 3. In addition, it appears that the recited geometric averaging is already required by claim 3.

Claim 5 lacks antecedent basis in claim 2 for the recited “connected clusters.” It appears that a word is missing in the last two lines in the phrase “first threshold the two clusters merged.”

Claim 6 is confusing in referring to a third threshold as claim 2 part a) only has one threshold. While claim 2 part b) refers to a second threshold, this claim makes it confusing as to whether part a) must be repeated twice (each time changing the threshold in a)) or something else.

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Claim 7 is grammatically unclear as to what is intended. It appears that at least one word is missing from the claims.

Claim 8, 10, 12, and 13 recites that the method “further comprises.” The claims do not make clear when or where within the method these steps are added. It appears that following all of the steps previously recited was not intended. In particular with respect to claim 8, what step (or steps) in claim 2 apply three standard measures of similarity. In particular with respect to claim 10, the claim recites “applying a numerical normalization to the SW, the FASTA and the BLAST.” Is this applied to the program itself or to the expectation value that results from the measure of similarity or something else?

Claims 9-13 are confusing in that the named measure of similarity are particular to sequence molecules (polynucleotide or amino acid) but claims 2-8 are not limited to these types of molecules.

Claim 27 is confusing in having two a) and two b) subparts. The claim is confusing as it implies that all molecules having similar structure have similar biologic function and that those molecules having similar biologic function are part of a biological family. However, the references to biological families is either redundant to the limitation of classifying molecules having similar biologic function or this recitation is intended to provide some additional limitation that is in some way different from this. Clarification is requested.

Claim 27 is also confusing in that the first database does not specify the type of molecules as being those with sequence while the second database refers to molecule sequences.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


Marianne P. Allen
Primary Examiner
Art Unit 1631
5/24/05

mpa